

# IPAC

## INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

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March 2, 2005

Dockets Management Branch  
Food and Drug Administration (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 03P-0029 – Proposed Rule: Use of Ozone-Depleting  
Substances; Removal of Essential-Use Designations

Dear Sir or Madam:

The International Pharmaceutical Aerosols Consortium (IPAC) is pleased to provide FDA with the following information regarding the Together Rx Access™ Card – a new program to assist uninsured Americans in obtaining needed prescription medications. Launched on January 11, 2005, Together Rx Access™ Card is a collaborative program created by 10 leading pharmaceutical companies, including three IPAC member companies.<sup>1</sup> It is relevant to FDA's pending determination on the non-essentiality of chlorofluorocarbon (CFC) albuterol metered-dose inhalers (MDIs), because it covers one of the three CFC-free albuterol MDIs on the U.S. market: Ventolin HFA®.

The Together Rx Access™ Card complements the Together Rx™ Card, initiated in 2002, which provides prescriptions savings for low-income Medicare beneficiaries. This new program provides significant savings to Medicare-ineligible patients on over 275 brand-name prescription medicines and products, as well as a wide range of generic

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<sup>1</sup> Together Rx Access, L.L.C. consists of the following pharmaceutical companies: Abbott, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, members of the Johnson & Johnson Family of Companies, Novartis, Pfizer, sanofi-aventis Group, Takeda, and TAP Pharmaceutical Products Inc.

products. Patients obtain instant savings ranging generally from 25-40 percent<sup>2</sup>, simply by presenting their Together Rx Access™ Card along with their prescription at the pharmacy counter.

The Card is available free to patients with no prescription drug coverage who:

- Are under 65 years of age and otherwise not eligible for Medicare;
- Have incomes of 300 percent or less of the federal poverty level;<sup>3</sup> and
- Are legal U.S. residents.

FDA has stated that as part of its determination on CFC albuterol MDI non-essentiality, it is examining whether the cost of CFC-free albuterol MDIs could make them effectively unavailable to a portion of the patient population.<sup>4</sup> As IPAC has previously stated,<sup>5</sup> several existing patient assistance programs will ameliorate much of the impact of such costs<sup>6</sup>. With the advent of the Card, an additional significant portion of the uninsured population is able to purchase Ventolin HFA® at greatly-reduced prices.

Eighty percent of the 45 million Americans who are uninsured and without prescription drug coverage – including more than 8 million children – are eligible for the Together Rx Access™ Card.<sup>7</sup> Thus, this program provides a significant additional

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<sup>2</sup> Savings may vary depending on the pharmacy's customary pricing for each specific product and the savings program offered by each participating company.

<sup>3</sup> Currently \$30,000 for a single person, \$60,000 for a family of four; \$38,000 single/\$50,000 couple in Alaska; \$35,000 single/\$45,000 couple in Hawaii. See U.S. Department of Health and Human Services, *Poverty Guidelines, Research, and Measurement*, available at <<http://aspe.hhs.gov/poverty/poverty.shtml>>, visited on February 11, 2005.

<sup>4</sup> Use of Ozone-Depleting Substances; Removal of Essential-Use Designations, 69 Fed. Reg. 33602, 33615 (June 16, 2004) (hereinafter "Proposed Rule").

<sup>5</sup> See International Pharmaceutical Aerosol Consortium (IPAC), *Comments on Notice of Proposed Rulemaking for Use of Ozone-Depleting Substances: Removal of Essential use Designations* at 3-4 (Aug. 12, 2004) (FDA Docket 03P-0029, Doc. C-22).

<sup>6</sup> See IVAX, *Comments on Notice of Proposed Rulemaking for Use of Ozone-Depleting Substances; Removal of Essential Use Nomination* (Jan. 12, 2005) (FDA Docket 03P-0029, Doc. EMC-42) and Schering Corporation, *Comments on Notice of Proposed Rulemaking for Use of Ozone-Depleting Substances; Removal of Essential Use Nomination* (Jan. 28, 2005) (FDA Docket 03P-0029, Doc. C-39).

<sup>7</sup> See Kaiser Commission on Medicaid and the Uninsured, *Health Insurance Coverage in America: 2003 Data Update* at 7 (Nov. 2004), available at <<http://www.kff.org/uninsured/loader.cfm?url=/>

benefit to the very patient subpopulation about which FDA has expressed concern in relation to the removal of CFC albuterol MDIs from the U.S. market.<sup>8</sup>

Participation in the program is very easy. A simple, two-page application is all that is required (see attached). Moreover, eligible participants will be able to use the Together Rx Access™ Card at a majority of U.S. and Puerto Rican pharmacies by mid-February 2005. In addition to the benefit provided directly by the Card, participants are automatically notified of other patient assistance programs provided by the program's 10 initiating pharmaceutical companies, providing yet further savings – and in some cases, free medicine – to eligible patients.

Then Secretary of Health and Human Services Tommy G. Thompson has praised the program, saying that it "will make life-saving and life-enhancing prescription medicines more affordable for millions of uninsured patients" and "is a common-sense, pragmatic way to give the uninsured access to prescription medicines."<sup>9</sup> IPAC believes that the Together Rx Access™ Card is yet another measure that will ensure that asthma and COPD patients who need albuterol MDIs will not be denied access to these life-saving products as a result of FDA's removal of ozone-destroying CFC albuterol MDIs from the U.S. market.

Sincerely,



Maureen Hardwick  
IPAC Secretary and Legal Counsel

#### Attachment

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*commonspot/security/getfile.cfm&PageID=49550>, visited on February 3, 2005; Alliance for Health Reform, *Health Care Coverage in America: Understanding the Issues and Proposed Solutions* at 7 (undated), available at <<http://covertheuninsuredweek.org/materials/files/IssuesGuide.pdf>>, visited on February 3, 2005; U.S. Census Bureau, *Income, Poverty, and Health Insurance Coverage in the United States: 2003* at Table 5 (Aug. 2004), available at <<http://www.census.gov/prod/2004pubs/p60-226.pdf>>, visited on February 3, 2005.*

<sup>8</sup> See Proposed Rule, 69 Fed. Reg. at 33607.

<sup>9</sup> Medical News Today, *New Together Rx Access™ Card Offers Americans With No Prescription Drug Coverage Savings At The Pharmacy Counter* (Jan. 11, 2005), available at <<http://www.medicalnewstoday.com/medicalnews.php?newsid=18818>>, visited on February 3, 2005.

Dockets Management Branch  
Food and Drug Administration  
March 2, 2005  
Page 4

cc: Robert Meyer (FDA)  
Eugene Sullivan (FDA)  
Randall Lutter (FDA)  
Wayne Mitchell (FDA)  
Lance Leggitt (HHS)  
Fume Yokota (OMB)  
Drusilla Hufford (EPA)  
John Thompson (State)  
Fran Du Melle (US Stakeholders Group)  
Pamela Wexler (US Stakeholders Group)

**ENROLLMENT FORM**You may also enroll online at [www.TogetherRxAccess.com](http://www.TogetherRxAccess.com)

First Name

M.I. Last Name

Address (Street Number / Street Name / Apartment Number)

City

State

Zip Code

Telephone

Date of Birth (mm/dd/yyyy)

Social Security Number

Gender:

☐ M ☐ F

Race: (Optional)

☐

Caucasian

☐

Black

☐

Asian

☐

Hispanic

☐

Other

Are you a legal US resident?

Yes ☐ No ☐

Are you eligible for Medicare?

Yes ☐ No ☐

Do you have prescription drug coverage of any kind (public/private)?

Yes ☐ No ☐

**HOUSEHOLD ANNUAL INCOME:** Please provide your annual (12 months) gross income from your last Federal Income Tax Return. If you did not file a tax return due to minimum filing requirements, please estimate your household income. \$

Note: If you are married and reside with your spouse, you must include both incomes regardless of tax filing status.

**SPOUSE (IF ELIGIBLE):**

First Name

M.I. Last Name

Gender:

☐ M ☐ F

Date of Birth (mm/dd/yyyy)

**DEPENDENTS (WHO MEET ABOVE ELIGIBILITY REQUIREMENTS):**

First Name

M.I. Last Name

Gender:

☐ M ☐ F

Date of Birth (mm/dd/yyyy)

First Name

M.I. Last Name

Gender:

☐ M ☐ F

Date of Birth (mm/dd/yyyy)

First Name

M.I. Last Name

Gender:

☐ M ☐ F

Date of Birth (mm/dd/yyyy)

First Name

M.I. Last Name

Gender:

☐ M ☐ F

Date of Birth (mm/dd/yyyy)

**MAY WE CONTACT YOU?**

By checking YES, you agree that Together Rx Access and its business partners may contact you about new programs and services, additional product and health information, or for market research purposes.

Yes ☐ No ☐

I have read, understand, and accept the Program Information including the limitations and authorization to use and disclose information sections on the back of this form. I certify that the information on this enrollment form is accurate and complete. I understand and agree that an Administrator of the Together Rx Access program may contact me in the future to verify this information.

Signature of Applicant or Representative

Signature of Spouse (if applicable)

Today's Date (mm/dd/yyyy)

## PROGRAM INFORMATION

### ENROLLMENT

I understand that Together Rx Access has hired an Administrator to administer the Together Rx Access program, who will review my enrollment form, determine my eligibility, and notify me based on the information I provide. The Administrator may at any time require additional information to determine or confirm my eligibility. If I am eligible, I will receive a membership packet and Card by mail.

### LIMITATIONS

Savings under the Program do not apply to prescription products reimbursed under any federal or state program, including Medicare or Medicaid ("Government Program"), or any private insurance, HMO, Medigap, employer, or other third-party arrangement ("Private Insurance"). By signing the enrollment form, I certify that I am not, nor are any of my family members listed on this application, eligible for Medicare, and I do not have prescription drug coverage through any government program or private insurance, nor do any of my family members listed on this application.

The Card may be used only for outpatient prescription products included in the Program. Participating companies independently determine which products to include and the savings offered. Products and savings may change at any time.

The Card may not be used with other prescription discount cards or pharmacy coupons. Coupons redeemed directly by a participating company are subject to the terms and conditions of the coupon.

The Card is valid only in the US and Puerto Rico. The Program may be terminated or modified at any time.

### AUTHORIZATION TO USE AND DISCLOSE INFORMATION

I understand that Together Rx Access and the Administrator will receive information about me and the prescription products that I receive using the Card. By signing this application, I authorize Together Rx Access and the Administrator to:

- use that information to administer the Program and to communicate with me, and
- share that information with participating companies for market research or analysis.

This authorization is in addition to any authorization that I have given under the heading "May We Contact You?" on the reverse side of this application. Together Rx Access does not provide/sell information that identifies you to third party companies not associated with the Program.

I may revoke this authorization by ending my participation in the Program by writing to Together Rx Access at the address provided in my membership packet.

### DEPENDENTS (WHO MEET ELIGIBILITY REQUIREMENTS):

First Name M.I. Last Name

First Name M.I. Last Name

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First Name M.I. Last Name

First Name M.I. Last Name

Gender: ☐ M ☐ F Date of Birth (mm/dd/yyyy)

Gender: ☐ M ☐ F Date of Birth (mm/dd/yyyy)

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